



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas ♦ PhytoPharmica  
Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY™**  
&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

April 26, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

MAY 12 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Pearl Essence™	Pearl Essence is a probiotic dietary supplement designed to help support digestion and a healthy intestinal system.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

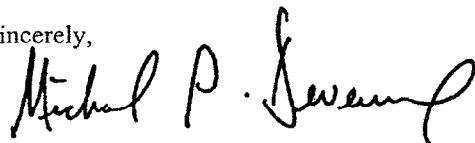
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

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April 27, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Pearl Essence™	While it is true that some types of bacteria are associated with disease and illness, friendly bacteria (such as found in Pearl Essence) are naturally found in the human intestine and play an important role in digestion and overall health.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

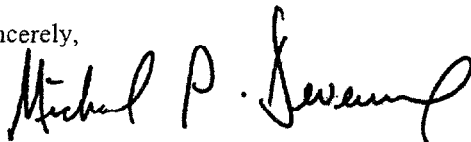
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

4/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux  
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Pearl Essence™	Supplemental, friendly probiotics help maintain a healthy microflora balance, and minimize the number of unfriendly bacteria.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

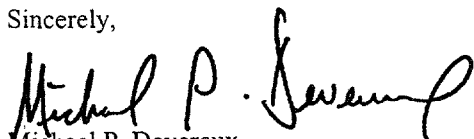
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

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Sincerely,



Michael P. Devereux  
Chief Financial Officer



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April 28, 2004

Office of Nutritional Products, Labeling &  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pearl Essence™	Clinical studies have shown that supplemental probiotic bacteria can help retain a healthy microflora balance both in the vagina and the digestive tract.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/28/04

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Sincerely,

Michael P. Devereux

Michael P. Devereux  
Chief Financial Officer